DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE --- FOOD AND DRUG ADMINISTRATION

GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 31, 2003
(See OMB Statement on Page 2)

PANEL MEMBER / PETITIONER
Medtronic Xomed Inc.

DATE
4/25/04

GENERIC TYPE OF DEVICE
Osmotic Cervical Dilator

CLASSIFICATION RECOMMENDATION
Class II

1 IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?	☐ YES	☒ NO	Go to Item 2
2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?	☐ YES	☒ NO	Go to Item 3.
3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?	☐ YES	☒ NO	Go to Item 4.
4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?	☐ YES	☒ NO	If "Yes," go to Item 6. If "No," go to Item 5.
5 IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☐ YES	☒ NO	If "Yes," Classify in Class I. If "No," go to Item 6.
6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* IN ADDITION TO *GENERAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?	☒ YES	☐ NO	If "Yes," Classify in Class II and go to Item 7 If "No," Classify in Class III.
7. IF THERE IS SUFFICIENT INFORMATION TO ESTABLISH *SPECIAL CONTROLS* TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS IDENTIFY BELOW THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II. ☒ Guidance Document ☐ Performance Standard(s) ☐ Device Tracking ☐ Testing Guidelines ☐ Other *(Specify)*			
8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY ANDEFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. ☐ Low Priority _____ ☐ Medium Priority _____ ☐ High Priority _____ ☐ Not Applicable _____			
9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD HE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN LACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	☐ YES ☐ NOT Applicable	☐ NO	
10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS ☐ Low Priority _____ ☐ Medium Priority _____ ☐ High Priority _____ ☐ Not Applicable _____			

11. IDENTIFY THE NEEDED RESTRICTION(S)

☒ Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device

☐ Use only by persons with specific training or experience in its use

☐ Use only in certain facilities

☐ Other *(Specify)*

13. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO.

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration, (HFZ-215)
2094 Gaither Road
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to , a collection of information unless it displays a currently valid OMB control number.